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No. 701

In the Supreme Court of the United States

OCTOBER TERM, 1964

DR. HENRY TUREK AND UROTICA CORPORATION,
PETITIONERS

v.

FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 12) is reported at 334 F. 2d 844.

JURISDICTION

The judgment of the court of appeals was entered on July 21, 1964. A petition for rehearing was denied on September 14, 1964. The petition for a writ of certiorari was filed on November 18, 1964. The jurisdiction of this court is invoked under 28 U.S.C. 1254(1).

757-901—64

QUESTIONS PRESENTED

1. Whether Section 505(h) of the Federal Food, Drug, and Cosmetic Act conferred jurisdiction on the court of appeals to review a decision of the Commissioner of Food and Drugs refusing to grant an investigational exemption from the new drug application requirements.

2. Whether the judgment of the court of appeals dismissing petitioners' appeal for lack of jurisdiction violated petitioners' right to due process under the Fifth Amendment to the Constitution.

STATUTE INVOLVED

Section 505 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1052, as amended, 21 U.S.C. 355 (Supp. V), provides in pertinent part:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.
>
> (b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing

of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

* * * * *

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for

the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator,

or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

* * * * *

STATEMENT

Petitioners are the developers and distributors of thirteen separate drugs collectively known as the "'U' Series Drugs," which are intended for use in the treatment of mongolism (R. 11a–12a).* The drugs are "new drugs" within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1041, as amended, 21 U.S.C. 321(p) (Supp. V). Under the provisions of Section 505(a) of the Act, no "new drug" may be introduced into interstate commerce unless an approved "new drug" application is in effect with respect to it. Other provisions of Section 505 prescribe procedures for obtaining approval of an application. No such application has been approved or is pending with respect to petitioners' drugs.

*Record references are to petitioners' printed Motion for Stay, filed with the court of appeals and made a part of the record in this Court.

Section 505(i) grants a limited exemption from the application requirements, conditioned on compliance with regulations promulgated by the Secretary, for drugs "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs."

Petitioners submitted to the Commissioner of Food and Drugs a notice claiming an exemption under Section 505(i) for the "U" Series Drugs (R. 5a). On submission of the notice the exemption became conditionally effective. The Commissioner notified petitioners that their notice was deficient (R. 2a), and petitioners corrected some but not all of the deficiencies. Thereafter, the Commissioner notified petitioners that "the conditions of exemption have not been met, and the exemption allowing clinical testing of the drug is terminated." Petitioners were advised that distribution and administration of the drugs to humans should immediately be discontinued (R. 1a). The Commissioner's action was discussed at an informal meeting between petitioners and representatives of the Food and Drug Administration but no change of position resulted.

The petitioners filed a petition to review the Commissioner's action in the court of appeals, invoking the court's jurisdiction on the basis of Section 505(h) of the Act. Respondent filed a motion to dismiss the petition on the ground that the court of appeals lacked jurisdiction to review the termination of an investigational drug exemption. After oral argument, judgment was entered dismissing the petition. The court of appeals held that the right of appeal granted

by Section 505(h) applies only to an order refusing or withdrawing approval of a new drug application and that the denial of an exemption under Section 505(i) could not be reviewed except by appeal from a subsequent denial of a new drug application. 334 F. 2d at 845–846.

ARGUMENT

1. It is clear from an examination of Section 505 that the provision of subsection (h) for review of "an order * * * *refusing or withdrawing approval of an application* under this section" (emphasis added) was intended to cover only new drug applications filed under subsection (b) and not action taken with respect to a request for an investigational exemption under subsection (i). The only "application" mentioned in the section is a new drug application, which is also the only document for which "approval" is expressly required (Sec. 505(a)) and for which there is provision for orders "refusing" (Sec. 505(d)) or "withdrawing" (Sec. 505(e)) approval.

Subsection (i) of Section 505, which provides for the investigational exemption, is placed *after* the provisions for review. Clearly, if Congress had intended to provide for review of actions taken under subsection (i) on the same footing as orders refusing or withdrawing approval of a new drug application, it would not have placed the provision for review where it did. Moreover, subsection (i) begins with a direction to the Secretary to promulgate regulations exempting drugs intended solely for investigational use "from the operation *of the foregoing subsections*"

(emphasis added), a reference which includes the provisions for review in subsection (h).

2. Petitioners' contention that the denial without a hearing of an investigatory exemption and the withholding of judicial review of such denial deprived them of due process of law is without merit. As this Court has repeatedly stated, "The demands of due process do not require a hearing, at the initial stage or at any particular point or at more than one point in an administrative proceeding so long as the requisite hearing is held before the final order becomes effective." *Opp Cotton Mills, Inc.* v. *Administrator,* 312 U.S. 126, 152–153. *Accord, Lichter* v. *United States,* 334 U.S. 742, 791–792; *Ewing* v. *Mytinger & Casselberry, Inc.,* 339 U.S. 594, 598. Petitioners have a full opportunity under the statute for a hearing (Sec. 505(c)) and for judicial review of the final administrative decision. The statutory scheme requires no more of petitioners, who have been denied an exemption from the requirement that new drug applications be filed and approved, than that they proceed with an application for approval of their drugs and thus develop a record which can be judicially reviewed.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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